Summary of Safety & Effectiveness
510K No. K003017
Grams Synthetic Absorbable Suture

MAR 1 3 2001

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92. This summary demonstrates the equivalence of Grams American Sutures to those of the legally marked devices listed.

A. Applicant:

Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024 USA

B. Contact Person: **A. J. Dimercurio**

C. Date Prepared: **October 25, 2000 (Original Submission 9/15/00)**

D. Device Name:

a. Trade Name: **Gramsorb™ Synthetic Absorbable Suture**
b. Common Name: **Polyglycolic Acid Absorbable Suture & PGA Absorbable Suture**
c. Classification Name: **Absorbable Poly (glycolide/l-lactide) Surgical Suture**

E. Predicate Devices:

1. **Polyglycolic Acid (PGA) Absorbable Surgical Suture (CP Medical) 510K # K002190**
2. **Polyglycolic Acid Surgical Suture (Trading Consultants & Dist.) 510K # K994001**
3. **Bondex Polyglycolic Acid Surgical Suture (Genzyme Surgical Prods.) 510K #K991191**
4. **PGA Polyglycolic Acid Synthetic Absorbable (Lukens Medical Corp.) 510K # K965162**

F. Device Description:

Gramsorb™ Synthetic Absorbable Suture is a synthetic absorbable, sterile, surgical suture composed of copolymers of Polyglycolic Acid. Gramsorb™ is a multifilament braided thread, undyed or dyed with an FDA listed color additive, D&C Violet No.2 (21CFR74.3602) and coated with a polycaprolactone, calcium stearate and sucrose fattyacid esters system.

G. Intended Use:

"Gramsorb™ is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures".

H. Technological Comparison to Predicated Devices:

Comparison Items	Grams American Suture Inc.	CP Medical	Trading Consultants & Dist.	Genzyme Surgical Products	Lukens Medical Corp.
Suture Material is composition of absorbable flexible, braided multifilament thread of homopolymers of glycolide	Same	Same	Same	Same	Same
Suture material is offered undyed and dyed with the FDA listed colorant, D&C Violet No. 2 (21 CFR 74.3602)	Same	Same	Same	Same	Same
Suture Material is supplied coated with a mixture of prolactone, calcium stearate, and sucrose fatty esters* to enhance it's handling properties.	Similar*	Similar	Similar	Similar	Similar
Suture material absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that Gramsorb™ retains approximately 50% of its original tensile strength at two weeks post implantation, with approximately 20% remaining at three weeks. Absorption of Gramsorb™ synthetic absorbable surgical suture is essentially complete between 60 and 90 days.	Same	Same	Same	Same	Same
The Suture Material is "Intended for Use" in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures	Same	Same	Same	Same	Same
Suture Material meets or exceeds the performance requirements for "Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia 23 and the current edition USP 24.	Same	Same	Same	Same	Same

* Note: Grams coating process uses a Food Grade Fatty Acid Ester, See enclosed Data

Comparison to Predicated Device Continued:

Comparison Items	Grams American Suture Inc.	CP Medical	Trading Consultants & Dist.	Genzyme Surgical Products	Lukens Medical Corp.
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Diameter" < 861 >	Same	Same	Same	Same	Same
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Tensile Strength" < 881 >	Same	Same	Same	Same	Same
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Needle ttachment" < 871 >	Same	Same	Same	Same	Same
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Suture Length Requirement"	Same	Same	Same	Same	Same
Grams Suture Material is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and USP XXIV.	Same	Same	Same	Same	Same

I. Conclusion:

Grams American Suture is composed of the same material, as are the predicate devices and the same design' being a sterile, flexible, braided multifilament threads meeting all the requirements of the United States Pharmacopeia. The Gramsorb™ Synthetic Absorbable Suture is manufactured in the same manner as the predicate devices, being produced from of homopolymers of glycolide (100%) and braided in operations considered standard in the fiber industry to form the finished suture fiber. The manufacturer supplies to Grams American Suture the same suture materials as it does to other suture manufacturers including some of those listed above.

The results of data presented and of the testing demonstrate the substantial equivalence of Gramsorb™ Synthetic Absorbable Suture to that of the predicated devices.

Gramsorb™ Synthetic Absorbable Suture meets the requirements of AAMI 10933-7: 1995, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.

Testing performed by Ethox Corporation; 251 Seneca Street Buffalo New York, 14204. Phone number for firm is 716-842-4000, Project Coordinator/ Lisa M. Luthart.

Attached is the test report on Gramsorb™ Synthetic Absorbable Suture ETO Residuals.

Grams Specified limits in ISO mg ADD (ETO & EC): 20,12 mg (limited use)
Grams Specified limits in ISO mg/day (ETO & EC): 2,2 mg/day (prolonged contact)

Addition information supplied and attached:

1. **Material Safety Data Sheet on Sucrose Fatty Acid Ester used in Gramsorb coating system.**
2. **Food-Grade Sucrose Fatty Acid Ester Manufacturers Product Data**
3. **Systemic Toxicity Test Results on Grams Coating System From Suture material Supplier "Gunze Limited" of Japan.**

A. J. Dimercurio
Grams American Suture, Inc.
Grafton Wisconsin 53024

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

Mr. A. J. Dimercurio
Vice President of Operations
Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024

Re: K003017
Trade Name: Gramsorb™ Synthetic Absorbable Suture
Regulatory Class: II
Product Code: GAM
Dated: January 11, 2000
Received: January 17, 2001

Dear Mr. Dimercurio:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GRAMS
American Suture, Inc.™

Intended Use Statement

K003017

"510(k) Notification"

21CFR 878.4493 21CFR 878.4493 Suture Absorbable Polyglycolic Acid

"Gramsorb™ is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures".

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003017